DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 9, 2014

Total Joint Orthopedics, Incorporated
Mr. Chris Weaber
Manufacturing Development Engineer
1567 East Stratford Avenue
Salt Lake City, Utah 84106

Re: K141972
Trade/Device Name: Klassic HD™ Acetabular Insert with E-Link™ Poly
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
Regulatory Class: Class II
Product Code: OQG, LPH, MBL, LWJ
Dated: July 18, 2014
Received: July 21, 2014

Dear Mr. Weaber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K141972 (pg 1/1)

Device Name: Klassic HD™ Acetabular Insert with E-Link™ Poly

Indications For Use:

The Klassic HD™ Acetabular Insert with E-Link™ Poly, for use within the Klassic HD™ Hip System, is intended for prosthetic replacement without bone cement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis, osteoarthritis, ankylosis, protrusio acetabuli and painful hip dysplasia.
- Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity or dysfunction persists.
- Revision of a previously failed hip arthroplasty.
- Patients who require a total hip replacement.

Prescription Use __X__ And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

SECTION 5
510(k) SUMMARY

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510(k) Notification K141972

GENERAL INFORMATION

Applicant:
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U.S.A.
Phone: 801-486-6070
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Contact Person:
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United States
Phone: 801-486-6070
Fax: 801-486-6117

Date Prepared: July 18, 2014

DEVICE INFORMATION

Trade Name:
Klassic HD™ Acetabular Insert with E-Link™ Poly

Generic/Common Name:
Hip prosthesis, UHMWPE acetabular insert with blended Vitamin E

Classification:
21 CFR§888.3358, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Product Code:
OQG Prosthesis, Hip, Semi-Constrained, Cemented, Metal/Polymer, + Additive, Porous, Uncemented)
LPH, Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented
MBL, Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Porous
LWJ, Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented

510(k) SUMMARY

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PREDICATE DEVICE(S)

- Total Joint Orthopedics Klassic HD™ Hip System (K100445)
- Pipeline Orthopedics Acetabular Liner with Vitamin E Poly (K112802)
- StelKast EXp Acetabular Shell Liner (K094035)

INTENDED USE

The Klassic HD™ Acetabular Insert with E-Link™ Poly is intended for use with the Klassic HD™ Hip System. The Klassic HD™ Hip System is intended for prosthetic replacement without bone cement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis, osteoarthritis, ankylosis, protrusio acetabuli and painful hip dysplasia.
- Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity or dysfunction persists.
- Revision of a previously failed hip arthroplasty.
- Patients who require a total hip replacement.

PRODUCT DESCRIPTION

The Total Joint Orthopedics Klassic HD™ Acetabular Insert with E-Link™ Poly ("Insert with E-Link") is a permanently implanted device for use as an acetabular bearing surface in total hip arthroplasty ("THA"). The Insert with E-Link is fully compatible for use with the previously cleared Klassic HD™ Hip System and is manufactured from Vitamin E blended UHMWPE crosslinked by gamma irradiation. The Insert with E-Link is sterilized by ethylene oxide gas and intended for single-use only.

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Klassic HD™ Acetabular Insert with E-Link™ Poly are similar to the predicate device. The design geometry, size availability, packaging and sterilization are equivalent to the predicate device. E-Link material characteristics and device performance data are provided to support the determination of substantial equivalence.

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NON-CLINICAL TESTING

Non-clinical bench testing was conducted on the Klassic HD™ Acetabular Insert with E-Link™ Poly to support a determination of substantial equivalence to the predicate devices. Bench testing included extensive material characterization before and after accelerated aging, abrasive wear testing, biocompatibility and sterility validation, and mechanical performance testing with the Klassic HD acetabular liner, femoral stem and femoral head.

All testing was performed in accordance with recognized standards when available. For testing where no recognized standard exists, non-recognized standards from ASTM and ISO were used as a guide. The collective results of the nonclinical testing demonstrate that the Klassic HD™ Acetabular Insert with E-Link™ Poly meets the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the Klassic HD™ Acetabular Insert with E-Link™ Poly is substantially equivalent and does not raise new questions of safety or effectiveness for total hip joint replacement when compared to the predicate devices.

SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate device are substantially equivalent to the proposed indications for use for the Klassic HD™ Acetabular Insert with E-Link™ Poly. The Klassic HD™ Acetabular Insert with E-Link™ Poly is similar to the predicate devices based on technological characteristics, design, material, non-clinical bench testing, sterilization and intended use. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the Klassic HD™ Acetabular Insert with E-Link™ Poly is substantially equivalent to the predicate devices.